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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/828,143	03/24/1997	HOUN SIMON HSIA	24400-101	4526

7590 04/22/2002  
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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/22/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/828,143

Applicant(s)

Hsia

Examiner

Irene Marx

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 28, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-11 and 36-42 is/are pending in the application.
- 4a) Of the above, claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 7/9/01 has been entered.

Claims 36-42 are being considered on the merits. Claims 16-20 and 24-35 are cancelled. Claims 9-11 are withdrawn from consideration as directed to a non-elected invention.

***Double Patenting***

Claims 36-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-24 of copending Application No. 08/879220. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each of the applications are directed to substantially the same nutritional composition comprising bacteria, yeast and protein in certain overlapping ranges.

Therefore the claims are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant indicates that a terminal disclaimer may be filed. In the absence of this document, the rejection is repeated.

Claims 36-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,294,166. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each of the applications are directed to substantially the same nutritional composition comprising bacteria, yeast and protein in a certain range.

Therefore the claims are co-extensive..

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36 and 37 are confusing in the recitation of "genus *Lactobacilli*". The correct genus designation is "*Lactobacillus*", as recited in dependent claim 37 with respect to the species designations. Claim 37 is confusing in the recitation of "strains" regarding the listing of species.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cajigas taken with Gonzalez Barberan, Levy, Prescott *et al.*, Fletcher *et al.* and The Merck Index and further taken with Jolly and Friend *et al.*.

Each of the Cajigas and Gonzalez Barberan references teaches a composition comprising dried viable bacteria, and a protein (See, e.g., Example, Col. 3-4, and col. 6-8, respectively). Note in particular that Gonzalez Barberan indicate that their product contains lactic acid bacteria and has favorable therapeutic properties. The dried, powdered instant yogurt product of Gonzalez Barberan is disclosed as having unlimited preservation without the need of refrigeration (Col. 4, lines 42-54). The container is presumed to be sealed for reasons of consumer safety.

The references differ from the claimed invention in that a non-living dried yeast is not included. However, Levy discloses nutritional or dietary composition comprising solid dried viable bacteria, dried, non-living yeast and naturally providing protein (See, e.g., col. 2, lines 29-35). The viable lactic acid bacteria are not disclosed as *Lactobacillus* strains. However, it is

well known that *Lactobacillus* strains are used for the production of yogurt, for example. The amount of bacteria appear to be within the claim designated range. Even though the brewer's yeast component is indicated at a higher percentage than claimed herein, and the protein content is not explicitly disclosed, dried brewer's yeast constitutes a valuable source of dried or concentrated protein. Prescott *et al.* adequately demonstrate that brewer's yeast is an art recognized source of protein. (See, e.g., bridging paragraph between pages 558-559). In addition, further dried viable lactic acid bacteria in the preparation are also a suitable source of protein and of nutrients to be administered as a nutrient supplement. Bacteria and yeasts biomass is art recognized as a source of protein, which is termed "single cell protein". It is apparent that the composition comprising dried bacteria packaged together with dried yeast as tablets retain viability, which does not decrease substantially. (col. 2, lines 29-35).

In addition, Fletcher *et al.* disclose bacteria suitable for the process of producing yogurt (See, e.g., Table 2) and teach that various yeasts can be added to yogurt, for example (See, e.g., col. 4, lines 55-58 and table 2). The addition of yeasts in dried inactivated form would have been obvious to one of ordinary skill in the art to gain the healthful benefits of yeast while avoiding the ingestion of potentially harmful live microorganisms. The Merck Index teaches that dried yeast are useful as a dietary supplement rich in vitamins and protein (page 1726). Thus, it is clear that the protein component not explicitly disclosed is present in the compositions of the references taken as a whole.

The references differ from the claimed invention in process parameters such as concentration of yeast and/or of protein. However, Jolly and Friend *et al.* disclose the advantageous combination of proteins, including whey and soy proteins with bacteria and/or yeasts for nutritional purposes. See, e.g., Friend *et al.*, page 128; Jolly, col. 3, lines 15-35. Note, in particular, the discussion throughout Friend *et al.* regarding the numerous benefits of providing *Lactobacillus* biomass for nutritional and therapeutic purposes. Jolly is cited to demonstrate that bacteria, yeasts and soy beans are all excellent sources of protein. (See, e.g., col. 3). Jolly teaches that various proteins can be added to food products such as yogurt (See, e.g., Col. 5, lines 35 to 45). The optimization of conditions identified as result-effective variables cited in the

references such as the concentration of the respective ingredients in the composition would have been prima facie obvious to a person having ordinary skill in the art.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition of Cajigas and Gonzalez Barberan by the addition of yeast in dried form as suggested by Levy and as suggested by the teachings of Prescott, Fletcher *et al.* and The Merck Index in addition to using a variety of protein sources and varying the proportions of ingredients in the nutritional composition as taught by Jolly and Friend *et al.* in view of the known benefits of administering bacteria, and *Lactobacillus* strains in particular, together with dried yeast and protein as a food such as in the form of yogurt, a product recognized to be palatable and easily digestible.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592, (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx  
Primary Examiner  
Art Unit 1651